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Public Health Service
DEPARTMENT OF HEALTH AND HUMAN SERVICES
HFI-35
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-03

October 19, 1998

John E. Cox, Owner
Cox Seafood Tarpon Springs, Inc.
P.O. Box 1973
Tarpon Springs, Florida 34688

Dear Mr. Cox:

On August 18, 1998, the Food and Drug Administration (FDA) conducted an inspection of your shrimp processing plant located at 1003 Roosevelt Boulevard, Tarpon Springs, Florida. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing shrimp being processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

> During the inspection, you told the investigator that the shrimp received at your firm most likely had been treated with sulfites. Consequently, undeclared sulfites are a hazard that is reasonably likely to occur in your product(s). However, your firm does not have and has not implemented a HACCP plan for controlling this hazard [21 CFR 123.6(b)]. At a minimum, such a HACCP plan would provide for monitoring of incoming shrimp to ascertain which lots contained sulfites and label declaration for sulfites, or in the case of bulk product, written notification to the prospective owner, for any outgoing product that contained sulfites. Please consult Chapter 19 of the Fish & Fisheries Products Hazard & Control Guides for more information.
>
> Failure to maintain sanitation control records that document the monitoring of all appropriate conditions and practices during processing with sufficient frequency to ensure proper sanitation [21 CFR 123.11(c)]. Specifically, there was no documentation of monitoring for plant water safety; condition and cleanliness of gloves, and outer garments; prevention of cross-contamination; maintenance of hand sanitizing facilities; protection from adulterants; proper labeling, storage and use of toxic compounds. In addition, the monitoring frequency of the sanitation areas, such as employee practices, were insufficient, and there was no documentation of corrective actions taken.

In addition, available sanitation control records fail to include the name of your firm, the date and time of the activity that the record reflects, and the signature or initials of the person performing the operation [21 CFR 123.9(a)].

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your processing plant. As the owner, it is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any seafood products processed by your firm until full compliance with the seafood and GMP regulations is achieved.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District